

II. REMARKS

Claims 12 to 17, 20 to 23, and 25 are pending. Claim 23 is amended; claim 24 is cancelled without prejudice to, or disclaimer of, the underlying subject matter. Support for the claim amendments may be found in the specification as filed. *See, for example, Specification* at page 82, line 18 to page 105, line 3. Therefore, no new matter is added.

Applicants thank the Examiner for the indication of allowability of claims 12 to 17 and the rejoinder of claims 20 to 25. Office Action at page 2.

Claim Rejection under 35 U.S.C. § 112, first paragraph (written description):

Claims 20 to 25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that “(n)o basis is seen for any of claims 20-25” and requests that Applicants point out by page and line number where every limitation of claims 20 to 25 can be found. Office Action at pages 3 to 4. Applicants respectfully traverse.

Claim 24 is cancelled and its subject matter incorporated into claim 23, which is amended. As an initial matter, Applicants respectfully submit that the specification as filed need not provide *in haec verba* support for new or amended claims. M.P.E.P. § 2163, M.P.E.P. (Rev. 5) at page 168. It is well-settled that the description of a claimed invention need not be *in ipsius verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751 (C.C.P.A. 1972).

The Examiner is correct that none of claims 20 to 25 require the nucleic acid to be associated with regulatory sequences. Office Action at page 3. The Examiner’s position is that

the specification does not disclose nucleic acids or transformed plants not associated with regulatory sequences. *Id.* Applicants respectfully disagree.

The specification as filed teaches that one method by which transformed plants can be created is using vectors that contain exogenous genetic material. *Specification* at page 83, lines 16 to 17. This vector may include regulatory elements. *Id.* at page 88, line 20 (emphasis added). In other words, the specification as filed provides written description to one of ordinary skill in the art on how to produce transformed plants comprising, for example, SEQ ID NO: 5 (exogenous genetic material), and that SEQ ID NO: 5 may or may not be associated with regulatory sequences. Therefore, the specification as filed fully supports at least claim 20, claim 22, amended claim 23, and claim 25, all of which claim, *inter alia*, plant(s) or plant cell(s).

With respect to claim 21, which claims, *inter alia*, a transformed host cell, the specification as filed provides written description to one of ordinary skill in the art on how to produce transgenic fungal cells (pages 105 to 117), mammalian cells (pages 117 to 122), insect cells (pages 123 to 131), and bacterial cells (pages 131 to 137). Once again, the exogenous genetic material introduced (*e.g.*, SEQ ID NO: 5) may or may not be associated with regulatory sequences. *See, e.g., Specification* at page 119, lines 19 to 20 (disclosing that one may use a variety of regulatory sequences such as promoter sequences and enhancer sequences in mammalian cells). In other words, one of ordinary skill in the art would recognize in the specification a description of the invention described in claim 21. *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). Therefore, the specification as filed fully supports at least claim 21.

In conclusion, Applicants respectfully submit that the specification as filed sufficiently describes claims 20 to 23, and 25 and respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement.

Claim Rejection under 35 U.S.C. § 112, first paragraph (enablement):

Claims 20 to 25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Office Action at page 4. Claim 24 is cancelled and Applicants respectfully traverse with respect to claims 20 to 23 and 25.

The Examiner's position appears to be the specification as filed does not teach how to use transformed host cells or plants that comprise SEQ ID NO: 5 because SEQ ID NO: 5 does not encode a full-length protein sequence. Office Action at page 4. Applicants respectfully submit that the issue is not whether SEQ ID NO: 5 does or does not encode a complete or biologically active protein. Nucleic acid sequences that do not encode complete proteins, or indeed, do not encode any proteins have well-recognized utility (*e.g.*, as promoter sequences, as other regulatory sequences, as encoding untranslated RNAs such as tRNA, RNAi, etc.) and thus one of ordinary skill in the art would know how to make and use such sequences in transformed cells. In other words, the Examiner's focus on whether or not SEQ ID NO: 5 encodes a full-length protein is incorrect.

With respect to claims 20 to 22 and 25, the Examiner states that "the specification does not provide any example of a transformed host cell or plant having the sequence of SEQ ID NO: 5." Office Action at page 5. Applicants respectfully submit that the presence or absence of an example specifically directed to SEQ ID NO: 5 cannot be a reason for a rejection under the enablement requirement of 35 U.S.C. § 112, first paragraph. Indeed, M.P.E.P. § 2164.02

explicitly states that “(c)ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. M.P.E.P. at page 189. Applicants submit that the specification as filed provided sufficient enablement for one of ordinary skill in the art to make and use the invention. *See, e.g., Specification* at page 55 *et seq.* In other words, claims 20 to 22 and 25 are fully enabled by the specification as filed.

With respect to claim 23, the Examiner states that “(n)o guidance is provided on producing a transgenic organism such as a cow, bird, or insect.” Office Action at page 5. Claim 23 is amended to, *inter alia*, a transformed plant and Applicants respectfully submit that this rejection is moot. In other words, amended claim 23 is fully enabled by the specification as filed.

In conclusion, Applicants respectfully submit that the specification as filed fully enables claims 20 to 23 and 25 and respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

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